510(k) SUMMARY

Winco, Inc.
Model Power Series Lift Chair

AUG 11 2008

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Winco, Inc.
5516 Southwest 1st Lane
Ocala, Florida 34474

Contact Person: James Ankoviak
President and COO
Winco, Inc.
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Ocala, Florida 34474
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Date Prepared: April 15, 2008

Name of Device and Name/Address of Sponsor

Winco Model Power Series Lift Chair

Winco, Inc.
5516 Southwest 1st Lane
Ocala, Florida 34474

Common or Usual Name

Lift Chair

Classification Name

Chair, Electric, Positioning

Predicate Device

Pride Mobility Model C5 Lift Chairs (K707950)

Intended Use

The intended use of the Winco Inc. Model Power Series Lift Chair is to assist persons who have difficulty rising from a seated position to a standing position.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Winco Models Power Series Lift Chairs are electro-mechanical devices designed for use in the home or a health care setting. Their intended function and use is to raise persons from a seated position to a standing position. They are designed for use by elderly or physically challenged individuals who have difficulty rising to a standing position, when seated.

The Winco Series Lift Chairs consist of two models; the model 696 lift chair and the model 905 lift chair. The model 696 chair is the standard version and is designed to accommodate most users. It is smaller and lighter than the model 905 chair, and has a maximum weight capacity of 300 lbs. The model 905 lift chair is designed for bariatric users. It is wider than the standard 696 lift chair and has a maximum weight capacity of 600 lbs.

B. Substantial Equivalence

The Winco, Inc. Model Power Series Lift Chair is substantially equivalent to the Pride Mobility Model C5 Lift Chairs

Performance Data

The Winco Power Lift Chair actuator has been tested to and meets the requirements of IEC 60601-1

The upholstery used in the Winco Power Lift Chairs meets the requirements of CAL 117 for Flame Retardancy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Winco, Inc.
% Mr. James Ankoviak
President and COO
5516 Southwest First Lane
Ocala, Florida 34474

AUG 11 2008

Re: K080533
Trade/Device Name: Winco Model Power Series Lift Chair
Regulation Number: 21 CFR 890.3110
Regulation Name: Electric positioning chair
Regulatory Class: Class II
Product Code: INO
Dated: April 11, 2008
Received: April 21, 2008

Dear Mr. Ankoviak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080533

Device Name: Winco Model Power Series Lift Chair

Indications for Use: To assist persons who have difficulty rising from a seated position to a standing position.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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